

Remarks

Claims 1-13 are pending in the subject application. By this Amendment, Applicants have canceled claims 1-13 and added new claims 14-24 (which correspond to the originally presented invention as it relates to SEQ ID NO: 437). Claims 23 and 24 relate to methods of using the polypeptides and compositions thereof and stand withdrawn from consideration. Support for the new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, paragraphs 70-75 at pages 17-18). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 14-24 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants acknowledge that the Patent Office may, where appropriate, require applicant, under 35 U.S.C. § 121, to elect claims to either the product or process and that claims directed to the non-elected invention are withdrawn from further consideration under 37 C.F.R. § 1.142. However, Patent Office policy related to the treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) indicates that if applicant elects claims directed to the product and the product is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product will be rejoined. With respect to this policy, Applicants respectfully submit that claims 23 and 24 relate to withdrawn process claims that include all the limitations of, or depend from, the product claims under examination in this matter (newly presented claims 14-22). Should the product claims currently under examination in this matter be found allowable by the Patent Office, Applicants respectfully request that the Patent Office rejoin claims 23 and 24 and that these claims be allowed as well.

As an initial matter, the Examiner has indicated that the first sentence of the specification or application data sheet should include a reference to the prior application from which benefit of priority is claimed, and also the status. Applicants further note that a Petition for an Unintentionally Delayed Claim of Priority has been submitted herewith and consideration of the petition is respectfully requested. In accordance with the Examiner's request, Applicants have amended the subject specification to indicate that parent U.S. application Serial No. 09/663,600 is now U.S. Patent No. 6,573,068. Applicants gratefully acknowledge the Examiner's helpful review of the

subject specification. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The Examiner has indicated that the title of the invention is not descriptive and that a new title is required that is clearly indicative of the invention to which the claims are directed. In accordance with the Examiner's suggestion, Applicants have amended the title of the invention to "Zinc Finger Binding Protein and Uses Thereof." Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

Claim 2 is objected to because of informalities. Specifically, the Office Action indicates that claim 2 recites non-elected inventions. Claim 2 has also been rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. By this Amendment, claim 2 has been canceled; thus, the objection and the rejection under 35 U.S.C. § 101 is moot. Accordingly, reconsideration and withdrawal of the objection and rejection is respectfully requested.

Claim 2 is rejected under 35 U.S.C. § 101 and under 35 U.S.C. § 112, first paragraph, on the grounds the claimed invention is not supported by a well-established utility and, thus, one skilled in the art would not know how to use the claimed invention. The Office Action argues that no specific, substantial, or credible utility has been disclosed for the claimed sequence (SEQ ID NO: 437). The Office Action further indicates that the benefit of prior application 09/663,600 has not been accorded to the claimed invention because the application fails to provide a patentable utility for the claimed invention and because the application fails to fulfill the enablement and written description requirements of 35 U.S.C. § 112. Applicants traverse the rejection as it applies to the newly presented claims.

As pointed out in the Office Action, the specification indicates that the claimed polypeptide is a zinc bind protein that has the ability to serve as a transcription factor or a signal transduction molecule (see specification at page 82, lines 14-17). The ability of the polypeptide identified as SEQ ID NO: 437 to serve as a transcription factor or a signal transduction molecule has been confirmed by Matsuda *et al.* (Oncogene, 2003, 3307-3318). As indicated in the publication, a polypeptide identical to SEQ ID NO: 437 is a transcription factor in the activation pathway of NF- κ B (Clone 266 disclosed in Matsuda *et al.* at page 3311, Table 4). As indicated in the publication, the polypeptide was able to activate transcription of a luciferase reporter gene driven by a promoter containing the

consensus NF- κ B binding sites (see Abstract and “Characterization of the Novel Genes”, pages 3310-3313). Accordingly, it is respectfully submitted that this article fully supports the assertions made in the as-filed application with respect to the asserted utilities of the claimed polypeptide as a transcription factor and that this reference can be relied upon to support the asserted utility of the claimed polypeptide (*see In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 U.S.P.Q. 367, 370 n.4 (C.C.P.A. 1971) later published references or other evidence may be used to demonstrate the accuracy or objective truth of statements made in the application as filed).

Applicants further submit that the claimed invention is enabled and also comports with the written description requirements of 35 U.S.C. § 112. As noted *supra*, the claimed polypeptide is able to activate transcription of a luciferase reporter gene driven by a promoter containing consensus NF- κ B binding sites. Thus, it is respectfully submitted that one skilled in the art would have known how to use the claimed invention in view of the teachings of the specification and the state of the art at the time the invention was made. Thus, it is respectfully submitted that the claimed invention is entitled to the priority date of the parent application and withdrawal of the written description and enablement rejections is respectfully requested.

Claim 2 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the Office Action argues that the as-filed specification fails to provide adequate written description for fragments of the claimed polypeptides. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention and traverse the rejection as it applies to the newly presented claims.

It appears that the Examiner considers the use of the transitional phrase “comprising” to result in the claiming of a large genus of polypeptides of SEQ ID NO: 437 that are not adequately described. Applicants have provided the polypeptide sequence required by the claims, *i.e.*, SEQ ID NO: 437, and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants were not in possession of the claimed polypeptides. For

example, the polypeptides (and fragments thereof) of the present invention may be fused with the constant domain of immunoglobulins (IgA, IgE, IgG, IgM), or portions thereof (CH1, CH2, CH3, any combination thereof including both entire domains and portions thereof) resulting in chimeric polypeptides (see specification at page 154, lines 20-33). Further, the specification indicates that chimeric proteins, such as antibodies fused to a polypeptide, or fragment thereof, comprising SEQ ID NO: 437 are contemplated as a part of the subject invention (see page 158, lines 23-32).

As the Patent Office is aware, the use of the transitional term “comprising” does not allow for internal alterations (*e.g.*, insertions or deletions) of the amino acid sequences set forth in SEQ ID NO: 437, but instead only allows for the addition of amino acids at either end of the polypeptide sequence. Alternatively, moieties, such as chemical groups, radiolabels or other markers can be attached to the claimed polypeptide fragments as is set forth in the as-filed specification at page 8, line 29 through page 9, line 17 of the published application. The fact that the claimed nucleic acid polypeptides may have other molecules attached or additional amino acids appended to the amino or carboxyl terminus of the sequence does not diminish the fact that Applicants have provided adequate written description of the claimed polypeptide sequences. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 2 is rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification on the basis that the claims refer to the ECACC deposit 98121805. Claim 2 is rejected under 35 U.S.C. § 112, second paragraph as, indefinite. As noted *supra*, the cancellation of claim 2 has rendered these issues moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first and second paragraph, is respectfully requested.

Claim 2 is rejected under 35 U.S.C. § 102(a) as anticipated by Kato *et al.* (WO 2001/149728, 2001). In addition, claim 2 is rejected under 35 U.S.C. § 102(e) as anticipated by Rosen *et al.* (U.S. Published Application No. 2002/0132753). While the cancellation of claim 2 renders the rejection moot, Applicants traverse the rejections as they may be applied to the newly presented claims. The Office Action indicates that the Kato *et al.* and Rosen *et al.* publications disclose a polypeptide that is 100% identical to the protein of SEQ ID NO: 437 of the subject specification. Applicants respectfully submit that the claimed invention is entitled to the benefit of a filing date of at least June 21, 2000 (as the claimed invention is described in U.S. Patent 6,548,633 at columns 69-70 [see SEQ

ID NO: 105] and PCT/IB00/00951 at pages 77-78 [see SEQ ID NO: 105]) and that the cited references are not available as prior art. Should the Patent Office assert that either reference is entitled to the benefit of one of the priority applications to which benefit is claimed, Applicants respectfully request that the Patent Office identify the provisional patent application and provide a copy of the same for Applicants' review. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

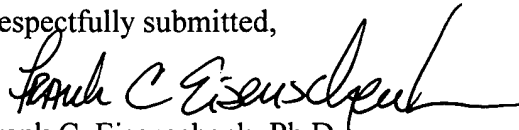
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/sl

Attachment: Petition for an Unintentionally Delayed Claim of Priority